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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,059	02/16/2001	Ronald C. Montelaro	A33577 072396.0217	4780

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NEW YORK, NY 10112

EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/785,059

Applicant(s)

MONTELARO ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____ .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claims 1-27 are pending and examined in this Office action. (Note that Claims 23-28 of the current application originally filed is subject to renumbering in accordance with 37 CFR 1.126, see below).

Objection to Specification/Claims

The disclosure is objected to because of the following informalities:

(1) The numbering of claims is not accordance with 37 CFR 1.126, which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claims 23-28 been renumbered 22-27.

(2) In page 6, line 5 of paragraph 9, “LBU” is noddod to be spelled out in full for the first instance of use. See also ‘MTT’ in page 20, line 5 of paragraph 51.

(3) In page 19, line 3, “5500⁻¹ m cm⁻¹” should be changed to “5500⁻¹ M cm⁻¹”.

(4) In Claim 27 (renumbered as stated above), “wherein microbial growth *in* resistant to antibiotics” should be changed to “wherein microbial growth *is* resistant to antibiotics”.

Corresponding correction is required.

Drawing

The drawing (Figures 1-12) filed 16 February 2001 is acceptable subject to correction of the informalities indicated on the attached “Notice of Draftperson's Patent Drawing Review,”

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PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

The following is the information on how to effect drawing changes.

1. New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948. All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

In addition, Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in abandonment of the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the term “having” which is an open-ended as opposed to the closed term “consisting of”. The claim is unclear as to whether or not the peptide as claimed is a genus that encompasses any peptide fragments comprising SEQ ID NO:1 or 2 or 3. The same are Claims 3, 5 and 7. The dependent claims are also rejected.

Claim 2 is unclear as to the recitation “one or more peptides”. The recitation “one or more” can be interpreted as any number more than one. Does the recitation refer to the peptide sequence(s) that is (are) not recited in Claim 1?

Claim 10 recites “low salt” which is an incomplete recitation. Does the claim refer to a low salt medium or buffer wherein the claimed peptide can optimally exert the antimicrobial activity?

Claim 12 is indefinite as to “at least one peptide”; the recitation is not apparent with respect to whether or not only one peptide, or two peptides with any combination number of SEQ ID NOs:1, 2 and 3, e.g. combination of SEQ ID NOs: 1 and 2, or combination of SEQ ID NOs: 1 and 3, or combination of SEQ ID NOs: 2 and 3, or three peptides SEQ ID NOs; 1, 2 and

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3 is (are) the component(s) of said solid phase substrate. See also Claim 24, which is renumbered (see Objection to the specification).

Claim 13 recites the limitation " the solid phase of Claim 12". There is insufficient antecedent basis for this limitation in the claim since Claim 12 does not recite "solid phase".

Claim 18 recites "at least one cysteine residue" which render the claim indefinite since the claimed SEQ ID NOs: 1-3 peptides contain only one cysteine residue recited in Claim 1.

Provisional Rejection - Obviousness Type Double Patenting

Claims 1-27 of this application conflict with Claims 1-7, 26-28, 35-42, 50, 54, 56 and 62 of Application SN: 10079075. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27 (renumbered, see the foregoing statement) of the instant application are provisionally rejected under the judicially created doctrine of double patenting over claims 1-7, 26-28, 35-42, 50, 54, 56 and 62 of Application SN: 10079075. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced application and would be covered by any patent granted on that application since the referenced application and the instant application are claiming common subject matter, as follows:

Claims 1, 2, 3, 4, 5, 6, 7, 26, 27, 28, 35, 36, 37, 38, 39, 40, 41, 50, 55, 56 and 62 of Application 10079075 claims the identical subject matter as Claims 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18, 19, 20, 21, 23, 25 26 and 27 of the instant application except the scope of claims differs. Claims 1, 35, 40, 42 and 54 of Application 10079075, which are Markush type claims consisting of 12 different peptides includes all the three peptides sequences SEQ ID NOS:1-3 of Claims 1, 12, 20, 22 and 24 of the current invention. Thus, the disclosure of the current application claims is obvious over that of Application 10079075 claims.

The subject matter of Claim 2 of the instant application has been disclosed in Claim 3 and Claim 5 taken with Claim 7 of Application 010079075. Claim 2 of the instant application sets

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forth a composition comprising one or more peptides (i.e. SEQ ID NOs: 1-3) of Claim 1 and a carrier. Application 10079075 discloses the identical composition but separately recites the composition in Claim 3 (for SEQ ID NO:1 peptide and a carrier), Claim 5 (for SEQ ID NO:2 peptide and a carrier), and Claim 7 (for SEQ ID NO:3 peptide and a carrier).

The subject matter of Claims 22 and 24 of the instant application has been substantially disclosed in Claims 42 and Claim 54 taken with Claim 55 of Application 010079075, respectively.

Claim 22 of the instant applicant sets forth a method for inhibiting microbial growth comprising administering an effective amount of the disclosed antimicrobial peptide(s). Accordingly, Application 10079075 discloses the same but with a subject, a mammalian cell, to which the antimicrobial peptide is administered.

Claim 24 of the instant application discloses the method of inhibiting microbial growth comprising administering to a subject the antimicrobial peptide(s). Claim 54 of Application 10079075 sets forth a method of inhibiting growth of microbial in a subject comprising contacting a cell of the subject with the disclosed antimicrobial peptide(s). Although Claim 54 does not explicitly disclose that the method of inhibiting microbial growth is carried out via administering the peptide(s) to the subject, Claim 55 of Application 10079075 sets forth more limitation for Claim 54 from which Claim 55 depends; the limitation regards administering the same antimicrobial peptide(s). Thus, The claim of the instant application and referenced application claims are obvious variation.

It is therefore concluded that the claims of the present application are not patentably distinct from the claims of Application 10079075.

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

It is noted that page 22 of the response filed 3 January 2002 requests abeyance of the obvious-type double patenting rejection until allowable subject matter is indicated. Note that no allowable subject matter can be indicated with a standing ground of rejection. Thus, it is suggested that applicant file the appropriate terminal disclaimer.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

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August 15, 2002

ACH
PONNATHAPUACHUTU MURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1653

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.